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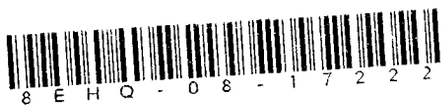
July 24, 2008




***Via Federal Express***

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004


**Subject:** Notice in Accordance with TSCA Section 8(e): Results of a Modified Developmental Toxicity Screening Study in Wistar Rats with N,N-Dimethylaminoethanol (CAS No. 108-01-0)

Dear Sir/Madam:

BASF Corporation and Taminco NV are submitting results of a pre-postnatal toxicity screening study in Wistar rats [Crl:WI(HAN)] with N,N-Dimethylaminoethanol (CAS No. 108-01-0), conducted by BASF SE, Ludwigshafen, Germany. The test substance is a high production volume chemical.

The aim of this screening was to obtain initial information on the effect of the test substance after repeated oral administration (gavage) to pregnant female Wistar rats

1) from gestation day (GD) 6 to GD 19 (prenatal study part) and

2) from GD 6 to postnatal day (PND) 3 (postnatal study part).

The pre-postnatal toxicity screening study was carried out with reference to the requirements of the following guidelines:

1. Prenatal study part:

- Corrigendum to EC Commission Directive 2004/73/EC, Part B: Methods for the determination of toxicity: Prenatal Developmental Toxicity Study; Official Journal of the European Union, No. L 216, pp. 227-235 (29 Apr 2004)
- OECD Guideline for Testing of Chemicals; Proposal for updating Guideline 414: Prenatal Developmental Toxicity Study (22 Jan 2001)
- EPA Health Effects Test Guidelines, OPPTS 870.3700: Prenatal Developmental Toxicity Study (Aug 1998)

as well as

2. Postnatal study part:

- OECD Guideline for the Testing of Chemicals; No. 421 (SIDS): Reproduction/Developmental Toxicity Screening Test (July 1995)
- EPA Health Effects Test Guidelines, OPPTS 870.3550: Reproduction/Developmental Toxicity Screening Test (July 2000)

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The test substance was administered to time-mated female rats orally by gavage from GD 6 through GD 19 (prenatal study part) or GD 6 through PND 3 (postnatal study part). The dose levels were 0 (control: 10 animals), 300 (dose group 1: 10 animals) and 600 mg/kg body weight/day (dose group 2: 20 animals).

For the prenatal study part, selected dams of each group (5 animals of the control group, 5 animals of dose group 1 and 10 animals of dose group 2) were sacrificed on GD 20; dams and fetuses were examined.

For the postnatal study part, the remaining dams were allowed to litter and rear their pups until PND 4. On PND 4, all pups were sacrificed and examined grossly.

The following is a summary of the most relevant results:

**Dose group 2 (600 mg/kg body weight/day):**

*Dams:*

- Salivation after treatment (20 out of 20 animals)
- Respiratory sounds (7 out of 20 animals)
- Statistically significantly reduced mean food consumption compared to the control group (set to 100%), i.e. between GD 6-8 (81%) and GD 8-10 (78%)
- Statistically significantly reduced mean body weight compared to the control group (set to 100%), i.e. on GD 13 (93%)
- Statistically significantly reduced mean body weight change compared to the control group (set to 100%), i.e. between GD 8-10 (52%)
- One animal sacrificed moribund on GD 14 (gross pathological examination revealed stomach erosions and no feces in intestine)
- One animal found dead on GD 20 (gross pathological examination revealed stomach ulcerations)

Prenatal study part (10 dams sacrificed on GD 20):

*Dams:*

- Increased post-implantation loss compared to the control group and the historical control data (11.8% vs. 5.2% in control)
- Stomach erosions/ulcera (8 out of 10 animals)
- Statistically significantly increased mean liver weight (118%) compared to the control group (set to 100%)

*Fetuses:*

- No test substance-related findings

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Postnatal study part (8 dams):

*Dams:*
- Stomach erosions/ulcera (8 out of 8 animals)
- One out of 8 animals did not deliver (7 animals left for further assessment)
- Salivation after treatment (7 out of 7 animals)
- Statistically significantly reduced mean food consumption (81% between PND 0-4) compared to the control group (set to 100%)
- Live birth index of 91% (control: 100%)

*Pups:*
- Six stillborn pups in 7 litters (64 pups *in toto*, 58 liveborn)
- Twenty-four pups out of 58 died ahead of schedule
- Nine pups out of 58 were cannibalized
- No more pups alive in 4 out of 7 litters (2 litters on PND 1, 1 on PND 2, 1 on PND 3)
- Viability index of 43% (control: 100%)
- Statistically significantly reduced mean body weight compared to the control group (set to 100%), i.e. on PND 1 (76%) and on PND 4 (71%)
- Statistically significantly reduced mean body weight change (57% between PND 1-4) compared to the control group (set to 100%)
- Twelve runts (no runt in the control)

**Dose group 1 (300 mg/kg body weight/day):**

*Dams:*
- Salivation after treatment (10 out of 10 animals)

Prenatal study part (5 dams):

*Dams:*
- Stomach erosions/ulcera (4 out of 5 animals)
- Increased post-implantation loss compared to the control group and the historical control data (15.2% vs. 5.2% in control)

- Increased resorptions (mean/litter) compared to the control group and the historical control data (1.4% vs. 0.6% in control)

*Fetuses:*
- No test substance-related findings

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Postnatal study part (5 dams):

*Dams:*
- Stomach erosions/ulcera (5 out of 5 animals)
- Salivation after treatment (5 out of 5 animals)

*Pups:*
- No test substance-related findings

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please call Janet Cerra at (973) 245-6693.

Sincerely,

*Janet Cerra*

Janet Cerra
Product Regulatory Center of Expertise
North America

/jc

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From: Origin ID: LKKA (973) 245-6693
Janet Cerra
BASF
100 Campus Drive

**Florham Park, NJ 07932**

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**Room 6428**
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